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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/491,624	01/26/2000	Carlos Picornell Darder	4948-2P/C/RCE	8816

7590 03/04/2005

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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 03/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/491,624	DARDER, CARLOS PICORNELL	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 15-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Request for Reconsideration received on December 23, 2004 is acknowledged. Claims 1-13 and 15-40 are pending in this application.

Response to Amendment

The applicant argues that the examiner has not addressed the Rule 132 Declaration filed 11/26/02. Firstly, it should be noted that the previous examiner did not address the Declaration since the rejection is over Depui et al and not EP 0642797. Thus, it is unclear why the applicant argues the unexpectedness of the instant invention over EP 0642797. Therefore, the demonstration that the instant invention is unexpected over EP 0642797 is moot.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-13, 26-29, and 37-38 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,132,771 to Depui et al.

Depui et al disclose an oral pharmaceutical dosage form comprising a proton pump inhibitor (abstract). More specifically, Depui et al disclose that the proton pump inhibitor can be selected from omeprazole, lansoprazole, pantoprazole, pariprazole, and leminoprazole. See column 4 to 6. Additionally, Depui discloses that the core material for their composition is a seed layered with the proton pump inhibitor along with an enteric coating. See column 8, lines 48-50. Depui et al. also teach that the seeds can be made of different materials, including sugars. See column 8, line 58. The reference discloses mixing the proton pump inhibitor with other components prior to layering on the seeds, wherein the components can include binders, surfactants, disintegrating agents, and fillers. See column 9, lines 1-5. The binder can be selected from HPM, HPMC, CMC, PVP, sugars and starches. See column 9, lines 3-6. The alkaline substance can be selected from sodium potassium, calcium, magnesium, and aluminum salts of phosphoric acid, carbonic acid, citric acid, and other weak acids, as well as magnesium oxide substances, and other substances normally used in antacid compositions. See column 9, lines 27-42. The surfactant disclosed is sodium lauryl sulfate. See column 9, lines 10. Lactose monohydrate and mannitol are utilized in the examples. Depui et al disclose that the seeds have a size between 0. 1 and 2 mm, which equals 100 to 2000 micrometers. See column 8, line 62. Most importantly, Depui et al state that their formulation does not necessarily include a spacing layer between the coated seed and an enteric coating. Depui et al disclose a middle, separating layer is **optional**, and the enteric coating can be applied directly to the coated core. See column 9, lines 46-50 and column 10, lines 41-43. The enteric coating layer is selected from I-IPMCP,

methacrylic acid polymers, HPMC acetate succinate, and shellac. See column 10, lines 46-53. Further, the enteric coating layer includes a plasticizer: PEG or cetyl alcohol, anti-tacking agents, and pigments. See column 10, lines 58-60 and column 11, lines 1-10.

Claims 15-25, 30-34, 36, and 39-40 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,365,184 to Depui et al.

Depui et al disclose an oral pharmaceutical dosage form comprising a proton pump inhibitor and an NSAID (abstract). More specifically, Depui et al disclose that the proton pump inhibitor can be selected from omeprazole, lansoprazole, pantoprazole, pariprazole, and leminoprazole. See column 4 to 6. Additionally, Depui discloses that the core material for their composition is a seed layered with the proton pump inhibitor along with an enteric coating. See column 8, lines 48-50. Depui et al. also teach that the seeds can be made of different materials, including sugars. See column 8, line 58. The reference discloses mixing the proton pump inhibitor with other components prior to layering on the seeds, wherein the components can include binders, surfactants, disintegrating agents, and fillers. See column 9, lines 1-5. The binder can be selected from HPM, HPMC, CMC, PVP, sugars and starches. See column 9, lines 3-6. The alkaline substance can be selected from sodium potassium, calcium, magnesium, and aluminum salts of phosphoric acid, carbonic acid, citric acid, and other weak acids, as well as magnesium oxide substances, and other substances normally used in antacid compositions. See column 9, lines 27-42. The surfactant disclosed is sodium lauryl sulfate. See column 9, lines 10. Lactose monohydrate and mannitol are utilized in the examples. Depui et al disclose that the seeds have a size between 0. 1 and 2 mm, which equals 100 to 2000 micrometers. See column 8, line 62. Most importantly, Depui et al state that their formulation does not necessarily include a

spacing layer between the coated seed and an enteric coating. Depui et al disclose a middle, separating layer is optional, and the enteric coating can be applied directly to the coated core. See column 9, lines 46-50 and column 10, lines 41-43. The enteric coating layer is selected from I-IPMCP, methacrylic acid polymers, HPMC acetate succinate, and shellac. See column 10, lines 46-53. Further, the enteric coating layer includes a plasticizer: PEG or cetyl alcohol, anti-tacking agents, and pigments. See column 10, lines 58-60 and column 11, lines 1-10. The examples utilize a Wurster-type fluidized apparatus to coat the active agent onto the sugar core, followed by an enteric coating. See example 4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-13 and 15-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,132,771 to Depui et al.

The teaching of Depui et al are set forth in detail above. Depui et al state that their formulation does not necessarily include a spacing layer between the coated seed and an enteric coating. Thus, Depui et al provides two embodiments, one for a optional separating layer and the second embodiment wherein the formulation implicitly does not contain a separating layer. Depui et al disclose a middle, separating layer is ***optional***, and the enteric coating can be applied directly to the coated core. See column 9, lines 46-50 and column 10, lines 41-43. Depui et al disclose the use of a fluid bed apparatus for coating. See examples. Depui states in the section titled "Background of the Invention" that it is known to formulate dosage forms containing only proton pump inhibitors or prokinetic agents respectively. Column 2, lines 25-31, the reference states that "combination therapy is considered for patients whose predominant symptom is regurgitation...those with respiratory problems...those with cough and hoarseness related to reflux disease."

With regard to the composition claims 1-13, 26-29, and 37-8, assuming one were to argue that Depui et al do not clearly anticipate the claims since Depui et al do not explicitly state that there is no separating layer, it is deemed obvious to one of ordinary skill in the art at the time the invention was made to make Depui et al's formulation with an inert core, ac active coating, and an enteric coating, excluding a the separating layer. One would have been motivated to do so since with a reasonable expectation of success since Depui clearly states that the separating layer is optional and thus the usage of the term "optional" is implicit that the formulation can functional stably without such a layer without a detrimental affect. Therefore, the removal of the separating layer is prima facie obvious to a skilled artisan.

With regard to claim 35 limiting the formulation to one active, the reference does not specify the use of only one active. However, it is deemed obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance of Depui et al and only utilize one active agent. One would have been motivated to do so since Depui et al clearly states that utilizing only proton pump inhibitors or prokinetic agents respectively is known and conventional and that combination therapy is utilized for patients with respiratory problems, reflux disease, etc. Therefore, it prima facie obvious to a skilled artisan that if a patient did not experience the symptoms as discussed by Depui, one would utilize a single active and Depui's alternative embodiment of combination therapy.

With regard to the process claims 15-25, 31-34, and 36, although Depui et al disclose the use of a fluid bed apparatus for the coating process, the reference does not state specify the type of fluid bed apparatus, i.e. Wurster-type fluidized bed apparatus. However, this is deemed obvious to one of ordinary skill in the art at the time the invention was made to utilize the appropriate type of fluid bed apparatus since these parameters are readily apparent to those skilled in the art and the criticality lies in the formulation of the composition and the process of coating onto the core. Thus, it is the examiner's position absent unexpected data, that the type of the apparatus used, i.e. Wurster-type fluidized apparatus versus a fluidized apparatus, does not impart a patentable difference since the prior art's apparatus provides the same function, i.e. the coating of layers onto the seed.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,132,771 to Depui et al in view of Lovgren et al (4,853,230).

The teaching of Depui et al are set forth in detail above. Depui states in the section titled "Background of the Invention" that it is known to formulate dosage forms containing only proton pump inhibitors or prokinetic agents respectively. Column 2, lines 25-31, the reference states that "combination therapy is considered for patients whose predominant symptom is regurgitation...those with respiratory problems...those with cough and hoarseness related to reflux disease."

The reference does not specify the use of only one active.

Lovegren teaches a pharmaceutical formulation of an acid labile substance for oral use. See abstract. The instant drugs are taught. See Table 1.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance of Lovgren et al and create a formulation with only a single active ingredient of a proton pump inhibitor. One would have been motivated to do so since Lovegren is relied upon to demonstrate the state of the art that it is known in the art to create formulations comprising a proton pump inhibitor as the single active. One would have been motivated to do so if one desired only single active therapy for treating the desired symptoms compared to combination therapy as taught by Depui. Therefore, this invention as a whole would have been prima facie obvious to one of ordinary skill in art at the time the invention was made.

Claims 15-25, 31-34, 36, and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,132,771 to Depui et al in view of Ohno et al (4,017,647) or Wurster (2,799,241).

The teaching of Depui et al are set forth in detail above. Depui et al disclose the use of a fluid bed apparatus for coating.

Depui et al do not specify the type of fluidized bed apparatus utilized.

Ohno et al teach a method for providing an enteric coating on solid dosage forms. The enteric coating solution contains those taught in Depui et al, i.e. film-forming polymers (HPMC), plasticizers, pigments, etc. on column 2. Ohno et al teach the use of a conventional coating machine such as pan coaters, drum-type coaters, or Wurster-type fluidizing caters, and Glatt fluidizing coater since there is no principle difference between coating solid dosage forms and all conventional coaters work under the same principle of utilizing a coating solution. See column 3, lines 24-40.

Wurster teaches the Wurster-type fluidized apparatus provides for a uniformed coating an preventing the coating material from sticking to the inner surface of the chamber. See column 1, lines 22-35.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Depui et al and Ohno et al and utilize the fluidized apparatus of choice such as instant Wurster-type. One would have been motivated to do so since Ohno teaches that the Wurster-type apparatus among other fluid bed coaters are known and conventionally utilized in the art for coating purposes and all the coating machines work under the same principle. Therefore, it is prima facie obvious to utilize the instant Wurster-Type in Depui's process with a reasonable expectation of success since not only does Depui teach the use of a fluid bed apparatus but Ohno teaches the equivalency of all coating machines.

Further, it would have been obvious to look at Wurster and utilize the instant apparatus. One would have been motivated to do so since Wurster teaches that the Wurster-type provides a uniform coating. Further, the Wurster patent demonstrates that the Wurster-Type apparatus is not

a new type of apparatus and as been known in the art since the 1940s. Therefore, it is reasonable for a skilled artisan to utilize a conventional machine routinely utilized in the pharmaceutical coating art, this does not impart patentability.

Claims 1-13, 26-29, and 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,365,184 to Depui et al.

The teaching of Depui et al are set forth in detail above. Depui teaches the use of the NSAID for its anti-inflammatory effects and the instant active for its gastric acid inhibition. Depui et al state that their formulation does not necessarily include a spacing layer between the coated seed and an enteric coating. Thus, Depui et al provides two embodiments, one for a optional separating layer and the second embodiment wherein the formulation implicitly does not contain a separating layer. Depui et al disclose a middle, separating layer is ***optional***, and the enteric coating can be applied directly to the coated core. See column 9, lines 46-50 and column 10, lines 41-43. Depui states in the section titled "Background of the Invention" that it is known to formulate dosage forms containing only proton pump inhibitors or prokinetic agents respectively. Column 2, lines 25-31, the reference states that "combination therapy is considered for patients whose predominant symptom is regurgitation...those with respiratory problems...those with cough and hoarseness related to reflux disease."

Depui et al does not specify the use of a single active agent, i.e. the anti-ulcer drug, with regard to the "consisting essentially of" language of independent claim 1.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to utilize Depui's anti-ulcer drug without the NSAID. One would have been motivated to omit an element and its function, it the element is not desired. Thus, in instant case it is obvious to

exclude Depui's NSAID if one did not desire to treat pain or inflammation and only wished to treat gastric disorder.

Response to Arguments Based on the 102 and 103 Rejections of Depui et al US 6,132,771 and US 6,365,184

Applicant's arguments field 12/23/04 have been fully considered but they are not persuasive.

1) Applicant argues that US patent 6,132,771, hereafter referred to as Depui et al, does anticipate the instant invention since Depui et al do not disclose or suggest a nonporous active layer. Applicant argues that Depui et al utilize an alkaline substance in the active layer and thus does not anticipate the instant invention.

Firstly, the examiner points out that the prior art does not have to expressly state that which is inherent or implicit. The examiner points out that the components that constitute the active layer are nonporous material. Further, the examiner points out that example's active material layer contain lanzoprazole, hydroxypropylmethylcellulose, sodium lauryl sulfate that is similar to the components of example 1 of the instant specification. Clearly, Depui's example 5's active layer does not contain an alkaline substance. Thus, the examiner points out that the active layer is inherently nonporous.

2) Applicant argues that Depui et al do not describe a stable and useful oral form of a proton pump inhibitor without an alkaline substance and at least one separating layer. It is argued that Depui fails to enable such a dosage form. Applicant claims that Depui et al never exemplify an embodiment without a separating layer or alkaline substance.

First, it should be noted that the applicant is wrong in his assertion that Depui does not exemplify a dosage form without an alkaline substance. The examiner points to example 5 wherein lanzoprazole is not in an alkaline form.

Secondly, it is pointed out that the Webster Dictionary defines *optional* as: involving an option: not compulsory. Further, option is defined as: 1) something that may be chosen 2) an item that is offered in addition to or in place of the standard. Thus, as noted by the applicant himself, the separating layer and alkaline substance are optional embodiments. The word "optional" in itself clearly denotes that if one were to exclude the *optional* separating layer and *optional* alkaline substance, it would not be detrimental to the dosage form. With regards to applicant's argument that if the separating layer and alkaline substance are excluded, then Depui et al would not be stable and thus not enabled. Again, it is pointed out that if the separating layer and alkaline substance were absolutely critical to Depui's invention, then Depui would not insert the word optional. Additionally, column 10, lines 29-220 is pointed out wherein Depui states, "the optionally applied separating layer(s) is **not essential** for the invention." Lastly, page 13 of instant specification should be noted since it also states that the inventive dosage form can include alkaline substances, just as Depui et al state the optional use of an alkaline substance.

Thirdly, the examiner points out that although Depui does not exemplify a dosage form without the optional separating layer, Depui discloses two options with the use of the word "optional", a dosage form with or without. Thus, a skilled artisan can immediately envisage the other form, i.e. the dosage form without a separating layer. Therefore, the courts have held that if one can immediately envisage an embodiment, then it is held to be anticipated. See In re Petering 133 USPQ 275 (CCPA 1962).

Lastly, with regard to the argument that Depui does not exemplify the instant invention, the examiner points out that disclosed examples and preferred embodiments do not constitute a teaching away form a broader disclosure or nonpreferred embodiment. See In re Susi. Therefore, even if for arguendo, the claims are not held to be anticipated by Depui et al, the claims are obvious since Depui et al clearly suggest the instant embodiments.

3) Applicant argues that cores that contain the alkaline substance must have a separating layer to be stable since the enteric coating contains free carboxyl groups, which can cause degradation of the omeprazole as taught by the prior art, Lovgren et al. Applicant argues that a side-by-side comparison of Lovgren and Depui et al demonstrates that a separating layer is required.

Firstly, the examiner is unclear as to why the applicant refers to Lovgren's disclosure when addressing the arguments based solely on Depui et al since Depui does not incorporate Lovgren's disclosure by reference. As discussed previously, Lovgren's formulation is not relied upon to make the rejection of instant invention's formulation. The only rejection made utilizing Lovgren et al is claim 35 wherein the examiner utilizes Lovgren to demonstrate the state of the art wherein it is known to utilize only a proton pump inhibitor as the sole active agent in an oral dosage form. Secondly, the examiner points out that the alkaline substance is optional and example 5 of Depui does not utilize an alkaline substance in the core. Therefore, as admitted by the applicant, a separating layer is only required if an alkaline core is utilized, it is clear that one can exclude this layer without a detrimental effect. Therefore, clearly Depui's disclosure that the separating layer is not essential to the instant invention, is applicable to example 5 and thus it is enabled.

4) Applicant argues that Depui et al (6365184) do not teach the Wurster apparatus.

First, it should be noted that the arguments discussed above are also applicable to US 6,365,184 to Depui et al. Secondly, as set forth in the rejection, the examiner points to example 4, line 24 wherein Depui teaches the use of a Wurster-fluid apparatus. Moreover, it is noted that only the process claims recite this limitation and not the product claims. Therefore, the distinguishable features argued by the applicant with regard to the product are moot.

Thirdly, the examiner points out that the applicant has not provided evidence demonstrating that a different and patentably distinguishable product is produced. The applicant relies on the specification's assertions to take the place of evidence and mere assertions without data to corroborate the statements, cannot overcome a rejection. Further, page 9 of instant specification is pointed out wherein applicant states that the: "Wurster" type fluid bed or the like in which the coating process is carried out minimizes the abrasion caused by rotogranulation. From this statement, it can be ascertained that the claimed bed coater only minimizes abrasion and does not provide for any distinct features as argued by the applicant.

Lastly, the applicant argues that the Depui et al's process requires multi-step process and the instant invention does not require this; however it is pointed out that the process claims recite open claim language that does not exclude Depui's steps. Thus, the instant process claims are not distinguishable from the prior art. For instance, page 16 of the arguments submitted 12/23/04 asserts that the instant invention does not encompass an extrusion/spheronization technique nor the powder layering process, however the claims do not recite this.

5) Applicant argues that the claimed invention as a whole is more stable since the enteric coating is stable because the active layer is homogenous and non-porous. Applicant argues that

the instant invention utilizes a Wurster type bed coater, which distinguishes it from the prior art. It is argued applicant utilizes effective parameters to accomplish this. The applicant argues that the examiner erroneously concludes that it is obvious to manipulate conditions.

The examiner previously stated that the use of "effective parameters" utilized in the instant invention, the examiner points out that it is obvious to one of ordinary skill in the art to manipulate the conditions set forth by the prior art to obtain the best possible results, which is still her position. However, it is pointed out that the applicant never specifically points out what this "effective parameters" are and the claims do not recite the parameters; therefore the issue whether the examiner has provided a motivation to manipulate the parameters is moot since the applicant has not recited any parameters, let alone the "effective parameters". Thus, applicant is relying on features that are not in the claims.

6) With regard to the "consisting essentially of" language, it should be first noted that the product claims only recite this language. The examiner points out that the process claims in which US 6365184 to Depui is applied, does not exclude additional layers or active agents. With regard to the product claims and US 6,132,771, the examiner points out that the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention and the exclusion of other active agents of different drug categories. The instant claim language does not exclude Depui's additional layers since they are not detrimental to the dosage form and as discussed above, are optional. Further, the separating layer is taught to be inert, which clearly falls under the umbrella of "not materially affecting the basic and novel characteristics".

Therefore, the rejections are maintained and the claims are not distinguishable over the prior art.

Response to Arguments Based on a 103 rejection over Depui et al in view of Lovgren et al

Applicant argues the merits of US patent 4,786,505, hereafter referred to as Lovgren et al. Appellant argues that Lovgren et al require a separating layer and alkaline substance; thus a skilled artisan would not be motivated to make a dosage form without the separating layer and alkaline substance.

Applicant's arguments have been fully considered but they are not persuasive. Firstly, the examiner relies upon Lovgren *solely* for the purpose of demonstrating the state of the art wherein a formulation containing only a single active, i.e. a proton pump inhibitor, is known in the art . The examiner does not rely on Lovgren's dosage formulation per se. Depui et al is utilized as the primary reference and discloses and suggests the broad aspect of the instant invention.

For argument sake, even if the secondary reference were removed, the examiner points out that Depui et al would still read over the prior art. Depui states in the section titled "Background of the Invention" that it is known to formulate dosage forms containing only proton pump inhibitors or prokinetic agents respectively. Therefore, the limitation of claim 35 is not a novel concept. It is acknowledged that Depui teaches the advantages of combination therapy (proton pump inhibitors and prokinetic agents); however "a known or obvious composition does not become patentable simply because it is described as somewhat inferior" See In re Gurley. Further, the examiner points to column 2, lines 25-31 wherein the reference states that "combination therapy is considered for patients whose predominant symptom is regurgitation...those with respiratory problems...those with cough and hoarseness related to

reflux disease." Therefore, it is quite clear to a skilled artisan that if a patient did not experience the above symptoms as discussed by Depui, one would utilize a single active. The combination therapy discussed by Depui is an alternative embodiment.

Response to Arguments Based on a 103 rejection over Depui et al in view of Ohno et al

Applicant argues that the Wurster-type fluidized apparatus provides for a uniform coating, which eliminates the need for a separating layer.

The arguments with regard to the Wurster-type fluidized are addressed above. Again the examiner points out that the applicant has not provided any evidence to substantiate the arguments.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SSG

Gary L. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600